RESPONSE

A. Status of the Claims

Claims 1-101 were pending at the time of the Action, with claims 2-4, 6, and 9-101 being withdrawn as being directed to non-elected inventions/species. Claims 2-9, 21-24, 27-30, and 47-100 have now been canceled. Claim 1 has been amended to include subject matter of claim 8. Claims 10-20 have been amended in view of the cancelation of claim 9 and the amendment of claim 1. New claims 102-105 have been added. Support for the amended and new claims may be found in the originally filed claims. Claims 1, 10-20, 25-26, 31-46, and 101-105 are now pending, with claims 10-20, 25-26, and 31-46 being withdrawn.

The Action indicated that SEQ ID NO: 124 was found to be free of the prior art (Action, p. 2). New claims 102-105 are directed to this sequence.

B. Amendment to the Specification

Applicant has amended the priority paragraph of the application to update the status of the parent application as "now abandoned."

C. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Action rejects claim 8 as being indefinite under 35 U.S.C. § 112, second paragraph. Specifically, the Action points out that SEQ ID NOs. 1-202 do not all comprise peptides as stated in the claim. Claim 8 has been canceled. Current claim 1, which recites certain SEQ ID NOs, recites only SEQ ID NOs that correspond to peptide sequences. Applicant, therefore, requests the withdrawal of this rejection.

D. Rejection Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1, 5, and 7-8 under 35 U.S.C. § 112, first paragraph, for lack of written description. In particular, the Action alleges that the description in the specification does

not adequately describe the genus of hydrophilic polymers or the genus of peptides encompassed by the current claims. Applicant traverses this rejection.

1. Hydrophilic Polymers

The phrase "hydrophilic polymer" is supported by adequate written description in the specification for at least the following reasons. First, hydrophilic polymers are discussed numerous times throughout the specification and originally filed claims (*see e.g.,* para. [0018], [0019], [0026], [0030], and [0059]; original claim 1). Second, the specification identifies a large number of hydrophilic polymers, such as agarose, dextran, heparin, chondroitin sulfate, hydroxyethyl starch, hyaluronic acid, poly(ethylene glycol), poly(ethylene oxide), poly(vinyl alcohol), poly(acrylic acid), poly(ethylene-co-vinyl alcohol), poly(vinyl pyrrolidone), poly(ethyloxazoline), and poly(ethylene oxide)-co-poly(propylene oxide) block copolymers. (para. [0025]-[0026]). One of ordinary skill in the art would understand from the specification and the general knowledge in the art that the genus of hydrophilic polymers share the common structural and functional properties of being polymers and of being soluble in water. Accordingly, the written description requirement for the genus of hydrophilic polymers is satisfied.

Furthermore, the Action's application of the written description requirement is legally flawed because it considers only the specific hydrophilic polymer described in the specification's working examples. The written description requirement for a claimed genus may be satisfied through sufficient description of a **representative number** of species. This does not, however, require the description to provide individual support for each species that the genus embraces (MPEP § 2163). Moreover, while the present specification does provide working examples, the Examiner is reminded that an actual reduction to practice is unnecessary to satisfy the written description requirement. *Falkner v. Inglis*, 448 F.3d 1357, 1364 (Fed. Cir. 2006); *see also* MPEP

§ 2163. Thus, the Examiner must consider the disclosure in the entire specification when determining whether the claimed invention is described in sufficient detail that one of ordinary skill in the art can reasonably conclude that the inventors had possession of the claimed invention at the time of filing.

Finally, in an opinion more recent than that in the *Eli Lilly* case cited in the Action, the Federal Circuit stated that "there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). In fact, a patent need not teach, and preferably omits, what is well known in the art. *Hybridtech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1987). Thus, an explicit recitation of known structure for well-known hydrophilic polymers, such as those recited in paragraph [0026] of the present specification, is not required under 35 U.S.C. § 112, first paragraph.

2. Peptides

Current claim 1 recites "one or more peptides selected from the group consisting of SEQ ID NOs 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 114, 120, 122, 124, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 200, and 202." The Action's written description rejection concerning the term "peptides" is moot in view of the language of the current claims.

3. Conclusion

In view of the above, the present specification describes the claimed invention in sufficient detail that one of ordinary skill in the art can reasonably conclude that the inventors had possession of the claimed invention at the time of filing.

E. Rejection Under 35 U.S.C. § 102(b)

The Action rejects claim 1 under 35 U.S.C. § 102(b) as being anticipated by Faanes (US 5,695,760). Applicant traverses this rejection.

Faanes is said to disclose a conjugate of PEG and a protein that binds to a ligand expressed on a cell surface (*i.e.*, an anti-ICAM-1 antibody). Faanes does not teach a peptide selected from the group consisting of SEQ ID NOs 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 114, 120, 122, 124, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 200, and 202. The Action acknowledges that Faanes lacks such a teaching by not including claim 8 in the present rejection.

In view of the above, Faanes does not teach all of the elements of current claim 1. Applicant, therefore, requests the withdrawal of this rejection.

F. Rejection Under 35 U.S.C. § 103(a)

The Action rejects claims 1, 5, and 7-8 under 35 U.S.C. § 103(a) as being obvious over Rieu et al. and Liu et al. The Action asserts that Rieu discloses a peptide having a sequence identical to SEQ ID NO:126 and that Liu teaches that integrins may be derivatized with PEG. Thus, the Action alleges that it would have been obvious to modify the peptide disclosed by Rieu by conjugating it to PEG according to Liu. Applicant traverses this rejection.

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Examiner still must provide an apparent reason to combine the elements in the fashion claimed by the applicant. *Id.* In making a determination as to whether a *prima facie* case of obviousness exists, the Examiner should: (A) determine the

scope and content of the prior art; (B) ascertain the differences between the prior art and the claims at issue; (C) determine the level of ordinary skill in the pertinent art; and (D) evaluate evidence of secondary considerations. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). These factual findings by the Examiner are the necessary underpinnings to establish obviousness. MPEP § 2141.

The current claims are patentable over Rieu and Liu. Current claim 1 is directed to a therapeutic bioconjugate comprising a hydrophilic polymer; and one or more peptides selected from the group consisting of SEQ ID NOs 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 114, 120, 122, 124, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 200, and 202. The Action does not allege that Rieu and Liu teach or suggest any of these peptides. Accordingly, a *prima facie* case of obviousness has not been established against the current claims.

Additionally, Rieu mentions that integrins may be a ***target*** for therapeutics (*see e.g.*, Abstract). More specifically, Rieu suggests that the further study of the structure, selectivity, and binding properties of the hookworm protein NIF may be useful in the design of therapeutically effective agents for the treatment of inflammation and hookworm infections (p. 2082; first column, first full paragraph). In regard to using an integrin itself as a therapeutic agent, Rieu merely speculates that "it is conceivable that the r11bA may be useful as such or in a modified form in treating hookworm infections" (p. 2090, first column, first paragraph). Such statements by Rieu would not provide a person of ordinary skill in the art a reasonable expectation of success.

In view of the above, the current claims are patentable over Rieu and Liu. Applicant, therefore, requests the withdrawal of this rejection.

G. Provisional Obviousness-Type Double Patenting

The Action provisionally rejects claims 1, 5, 7-8 for obviousness-type double patenting over co-pending Application No. 11/244,536 in view of Rieu and Liu. A provisional double-patenting rejection, however, is not a final rejection that blocks the prosecution of all of the conflicting applications. If a provisional double-patenting rejection is the only rejection remaining in an application, the Examiner should withdraw the rejection and permit the application to issue as a patent. MPEP § 804(I)(B). After one application issues as a patent, the provisional double-patenting rejection in the remaining application is converted to an actual double patenting rejection. Id. Thus, either the present application or the '536 application must issue as a patent before an actual double patenting rejection may be raised against the remaining application. Applicant will consider filing a terminal disclaimer, if appropriate, at that time.

H. Conclusion

Applicant believes this to be a complete reply to the Office Action dated January 7, 2008, and respectfully requests favorable consideration of the claims in view of the amendments and statements contained herein. Should the Examiner have any questions or comments regarding this matter, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,

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